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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,977	06/28/2000	Joseph R. Byrum	16517.144/38-21(15877)B	6609

7590

04/08/2003

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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/606,977

Applicant(s)

BYRUM, JOSEPH R.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 20-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 8-19 have been cancelled. Claims 20-24 have been newly added.

Applicant's arguments filed 1/7/03 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1 and 4 under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No. AI834598 (02-FEB-2000) is withdrawn. The examiner has verified that SEQ ID NO: 1 of the instant application corresponds to SEQ ID NO: 1 of provisional application 60/141,233. (See attached page of sequence listing from 60/141,233.)

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification. The provisional application does not appear to be referenced.

Claim Rejections - 35 USC § 101

Claims 2-3 and 6-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 2-3 and 6-7 have been amended to indicate that the nucleic acid molecule according to claim 1 "further comprises" an additional element. None of the portions of the specification pointed to provide support for these concepts. The originally filed claims and

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specification recite that the nucleic acid molecule according to claim 1 itself contains or is each of these elements.

Claims 1-7 and 20-24 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

The sequence listing identifies SEQ ID NO: 1 as a 280 nucleotide DNA sequence with at least one wild-card nucleotide position from *Zea mays*. Table A on page 18 indicates that SEQ ID NO: 1 corresponds to clone ZM_001_A1_A01 with SEQ ID forward as ZM_001_A1_A01_T7C. These designations are not further explained.

There does not appear to be a direct assertion as to how to use SEQ ID NO: 1 nor identifying the particular functional characteristics of the sequence. While the specification generally states that SEQ ID NOS: 1-82359 encode proteins (see page 10), the specification also states that SEQ ID NOS: 1-82359 are promoters (see page 11) and that SEQ ID NOS: 1-82359 are markers (see page 12). These are mutually exclusive classes of nucleotide sequences. For example, promoters do not encode proteins. As such, the specification does not fairly identify what SEQ ID NO: 1 is and as such, the specification cannot be considered to disclose how to use it without confirming any one of these uses or identifying an undisclosed use. Note that the specification does not disclose an open reading frame for SEQ ID NO: 1 nor is one apparent. Note that the specification does not disclose that SEQ ID NO: 1 is a repetitive sequence in *Zea mays* that has been shown to be a marker of any trait. SEQ ID NO: 1 does not appear to share significant structure with any known marker of *Zea mays*. Note that the specification does not

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disclose a promoter activity for SEQ ID NO: 1 with respect to any encoded protein. SEQ ID NO: 1 does not appear to share significant structure with any known promoter. It is noted that applicant's response failed to address any of these facts. Based upon the extremely limited disclosure of the specification, applicant does not appear to have identified any function for SEQ ID NO: 1.

Applicant states in the response that "one of ordinary skill in the art can discern from the specification and from the sequence listing the class of nucleotide sequences into which SEQ ID NO: 1 falls." However, the examiner notes that the specification does not disclose which class it falls into and that applicant has declined to identify which class it falls into in the response. Applicant is specifically invited to identify which class it falls into. Failure to do so will be considered non-responsive.

Applicant further compares the claimed invention to a microscope.

A microscope is useful for determining structure of *any* sample of interest at the macroscopic, microscopic or molecular level, depending on the type of microscope. It is a generally useful tool for a wide range of specific uses. One does not usually use a microscope to study related microscopes. In contrast, applicant argues that the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell, or organism. Further research and experimentation would be required to identify a full length sequence that encoded a full-length protein and its function, to identify any promoter present, or to determine any genetic markers of *Zea mays* present in SEQ ID NO: 1. Further experimentation would be required to use SEQ ID NO: 1 to find related sequences, genetic markers or polymorphisms. Applicant argues that the claimed nucleic acid molecules can be

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used as genetic markers, in physical mapping, to identify polymorphisms, and to monitor expression. Further experimentation would also be required for these uses. Applicant appears to be arguing that the claimed invention is a research tool or usable as a laboratory reagent. Laboratory reagents must be sufficiently characterized and their properties understood to be used in these ways. In the absence of such characterization, no meaningful information is provided. The claimed nucleic acid molecules are starting materials for further research and not research tools. Identifying and studying the properties of the claimed subject matter itself or the mechanisms in which the claimed subject matter is involved does not define a "real world" context or use.

It is noted that a "polymorphism" is a collective concept defined by at least two variants (or alleles) found within members of a species collectively. Thus, one detects the *presence* of a polymorphism by analyzing multiple members of the species, i.e. analyzing a population. While one can detect the absence (or presence) of a specific allele of the polymorphism in a specific individual member of the species, one cannot detect the *absence* of a polymorphism *per se* based on one individual alone. The absence of a particular allele necessarily means that a different allele is present. The specification fails to disclose a specific and substantial utility for the claimed invention in the capacity of detecting polymorphisms, because it does not disclose whether the claimed nucleic acid molecules can, in fact, be used to detect any polymorphism whatsoever. Thus, the specification leaves open the possibility that there may be no polymorphism to detect.

It is noted that the specification discloses *no* nucleic acid molecule that hybridize with the claimed nucleic acid molecule that does *not* consist or comprise SEQ ID NO: 1 or its

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complement. In order for hybridization between two nucleic acid molecules to occur, they must share at least some nucleotide sequence that is fully complementary. The length of fully complementary sequence required to detect hybridization depends primarily on the stringency of the specific hybridization conditions employed, the lower the stringency the shorter the length of fully complementary sequence required. The specification also fails to disclose any hybridization conditions required for detecting nucleic acid molecules that do *not* contain the nucleotide sequence of SEQ ID NO: 1 or its complement, in addition to failing to disclose any source for such nucleic acid molecules. Even if sequences other than SEQ ID NO: 1 that met the structural requirements of the claims were found, one skilled in the art could not use the claimed discovery in a manner which provides some *immediate* benefit to the public (*Nelson v. Bowler*, 206 USPQ2d 881, 883 (CCPA 1980)). A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. *Brenner v. Manson*, 148 USPQ 689, 696 (USSC 1966).

Insofar as the specification fails to describe a specific, substantial, and credible utility for SEQ ID NO: 1 itself, so does it fail to describe a specific and substantial utility for the nucleic acid molecules that hybridize to SEQ ID NO: 1 (see for example claim 1), are complementary to SEQ ID NO: 1 (see for example claim 1), contain additional elements (see for example claims 2-3 and 5-7), are fragments of SEQ ID NO: 1 (see for example claim 21), or have a level of similarity with SEQ ID NO: 1 (see for example claim 23).

Claims 1-7 and 20-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible

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asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The uses asserted for the claimed invention are methods where the claimed invention is, itself, an object of scientific study. The specification cannot enable or tell how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. The Examiner maintains that there is no patentable utility for the claimed invention for the reasons set forth above and thus the claims are not enabled.

Claims 20 and 24 are ejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 20 recites "comprises a nucleic acid molecule consisting of." The juxtaposition of open and closed language is confusing and "comprising" is considered to control the scope of the claim. This claim does not appear to further limit the subject matter of claim 4 which recites "comprises." Applicant is requested to explain how these claims differ in scope.

Claim 24 is confusing in being dependent upon itself. This appears to be an error.

Claim Rejections - 35 USC § 102

Claims 1, 4, 20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by NCBI Accession No. S42508 (08-May-1993).

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NCBI Accession No. S42508 discloses a nucleotide sequence from *Zea mays*. This sequence would hybridize under the low stringency conditions of claim 1 to a second nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1 or a complement. Note that the use of the article "a" includes subsequences of SEQ ID NO: 1. These subsequences could be as small as a single nucleotide. Likewise, claims 4, 20, and 23 encompass a nucleic acid molecule having a single nucleotide in common with SEQ ID NO: 1 or its complement.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

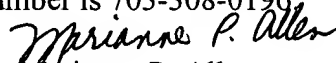
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196

A handwritten signature in cursive script that reads "Marianne P. Allen".

Marianne P. Allen

Primary Examiner

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mpa

April 2, 2003